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Does Insertion Torque Affect the Mechanics of Locking Hole Inserts and Fatigue Performance of Bridge Plate Constructs?

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Summary

Placing locking hole inserts into empty plate holes over the zone of comminution theoretically improves the fatigue properties of the construct. The purpose of this investigation was twofold: first to evaluate fatigue performance of locking plates instrumented with locking hole inserts (LHIs), and second to determine if increased insertion torque improves performance. New LHIs designed specifically to reduce the likelihood of loosening were utilized in this study in ASTM

four-point bend loading scenarios. Plates with LHIs were tested for both stiffness and fatigue properties. The results of this study indicate substantial improvement in the cycles to failure for both 3.5 mm and 4.5 mm plates. Additionally, increasing insertion torque was an advantage in both fatigue life and loosening of the inserts. Their use in regions that span bony defects, particularly in patients in whom delayed fracture healing may be present, may be advantageous.

Introduction

Empty screw holes over the zone of metaphyseal or diaphyseal comminution in plate-screw constructs may be necessary based on the fracture pattern. While leaving more holes open may disperse stress through these holes and aid in secondary bone healing, they are still stress risers and in instances of delayed union or non-union can become a weak link in the fatigue strength of the construct, potentially leading to plate failure [1,2]. When using a plate with round locking holes, it has been shown that placing

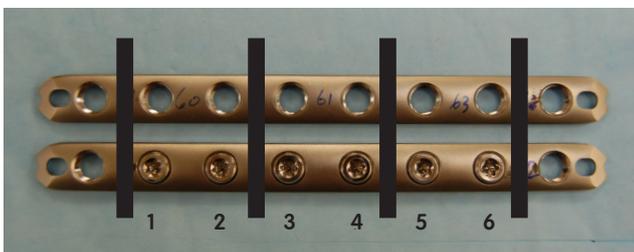
locking screw heads (shaft of standard screw cut off) into open holes improves fatigue properties as the plate in this region acts more like a solid plate [3]. However, these modified cut off screw heads may be prone to loosening. The purpose of this investigation was twofold: first to evaluate fatigue performance of locking plates instrumented with contoured locking hole inserts (LHIs), and second to determine if increased insertion torque improves performance.

Methods

New LHIs were designed specifically to reduce the likelihood of loosening. Their engagement with plate screw hole threads results in an increased friction over normal screw heads, while still allowing for ease of removal. The mechanical performance of both 3.5 mm and 4.5 mm 8-hole locking plates (PERI-LOC[®], Smith & Nephew Inc., Memphis, TN, USA) instrumented with new LHIs was evaluated using four-point bend per ASTM standards [4]. Plates were tested for both stiffness and fatigue properties. All plates were positioned in a worst-case configuration during loading such that the undersurface of the plate (the side facing bone) was in compression. For each size, plates instrumented with six LHIs were compared to plates with all holes open. Two LHIs were located within the loading span (seeing a constant load) and four were outside the loading span but saw bending stress (Figure 1). The 3.5 mm LHIs were inserted to either 1.70 N-m or to 3.96 N-m, which represent two of the standard recommended insertion torques. The 4.5 mm LHIs were inserted to 3.96 N-m only.

Quasi-static loading within the elastic limit of the constructs was carried out by utilizing a ramp function displacing 5 mm/min. Sinusoidal cyclical fatigue loading at 3 Hz was then performed. Upon fatigue failure (defined as plate fracture), the amount of LHI loosening was evaluated by measuring removal torque. Statistical analyses for means were performed on test results using an F-Test for variance and a Student's t-Test assuming equal variance.

Figure 1: Locking compression plate w/ and w/o LHI



The SS PERI-LOC Locking Compression Plate with and without Locking Hole Inserts as tested (3.5mm plate shown with numbered holes and approximate location of loading rollers and spans indicated)

Results

Failure mode

Every plate fractured through one or more of the locking screw holes located within the loading span (Figure 2).

Stiffness

There was no difference in stiffness for 3.5 mm ($p = 0.36$) or 4.5 mm ($p = 0.73$) plates with the introduction of LHIs.

Effect of fillers and insertion torque

For the 3.5 mm plates with 1.70 N-m insertion torque, the plates with LHIs had a 52% increase in the cycles to failure ($114,300 \pm 23,680$ vs. $75,487 \pm 15,746$ cycles; $p = 0.01$). Increasing insertion torque to 3.96 N-m led to a further increase in 3.5 mm plate fatigue life ($p = 0.02$) to an average $155,177 \pm 32,493$ cycles. This represented a 106% increase compared to plates without LHIs ($p < 0.05$) (Figure 3). Likewise, the 4.5 mm plates with LHIs demonstrated a 48% increase in their cycles to failure ($74,369 \pm 10,181$ vs. $50,214 \pm 5,544$ cycles; $p = 0.001$) (Figure 4).

Loosening of inserts

At the 1.70 N-m insertion torque, all 3.5 mm LHIs inside the loading span had nearly completely loosened (removal torque < 0.2 N-m) upon failure. Increasing insertion torque to 3.96 N-m reduced loosening to 63% of insertion torque, despite a higher cycle count at plate failure. The 4.5 mm LHIs retained on average 64% of their insertion torque at failure.

Figure 2: Representative failure mode of plates



Typical Fracture of the SS PERI-LOC Locking Compression Plate with and without locking screw hole fillers (4.5mm plate shown here).

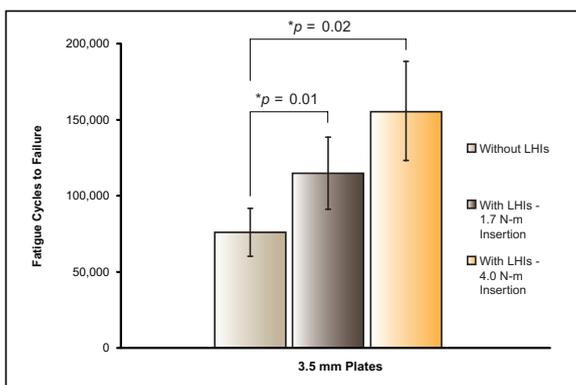
Discussion

Locked plating technology has expanded the versatility for meta-diaphyseal fractures by providing angularly stable fixation of the distal segment. However, with the advances in fixation of the plate to bone, the failure mode clinically has largely shifted to plate fatigue. This is most evident in segmental defects of the distal femur and proximal tibia [5-7]. These defects take a long time to heal and many need delayed grafting procedures. Holes that are within the defect region of the plate become stress risers and are the most common region for fatigue failure of the plate. In theory, inserting a LHI will make the region over the defect stronger since LHIs are mechanically fit into a threaded hole. The goal of these inserts is to increase the fatigue life of the implant in the face of a defect. The results of this study indicate substantial improvement in the cycles to failure for both 3.5 and 4.5 plates. Additionally, increasing insertion torque was an advantage in both fatigue life and loosening of the inserts. Their use in regions that span bony defects, particularly in patients in whom delayed fracture healing may be present, may be advantageous.

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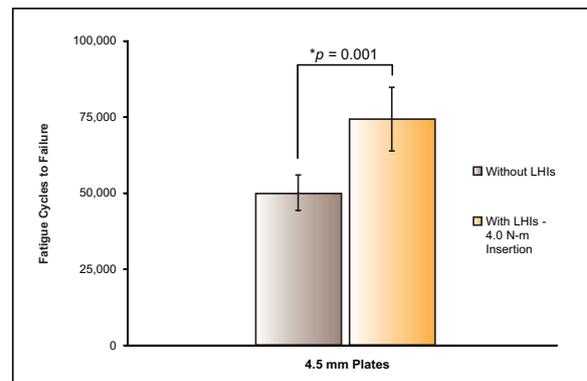
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Figure 3: 3.5 mm plate failure data



Increased plate fatigue cycle count with 3.5mm LHIs.

Figure 4: 4.5 mm plate failure data



Increased plate fatigue cycle count with 4.5mm LHIs.

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